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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/529,352	01/11/2006	Nigel Tooke	21465-523 NATL	2533
35437 7590 12/10/2008 MINTZ LEVIN COHN FERRIS GLOVSKY & POPEO ONE FINANCIAL CENTER BOSTON, MA 02111				
EXAMINER WOOLWINE, SAMUEL C				
ART UNIT		PAPER NUMBER		
1637				
MAIL DATE		DELIVERY MODE		
12/10/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/529,352

Applicant(s)

TOOKE, NIGEL

Examiner

SAMUEL WOOLWINE

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 September 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7, 9-11, 14-18, 20 and 23-35 is/are pending in the application.
- 4a) Of the above claim(s) 9, 10 and 27-35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 14-18, 20 and 23-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 09/12/2008 has been entered.

Status

Claims 1-7, 9-11, 14-18, 20 and 23-35 are pending in the application. Claims 9, 10 and 27-35 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention and/or species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 09/27/2007.

Any previous rejection of a claim which has been cancelled is withdrawn as moot.

The rejection of claims 1-7, 14-18 and 25 under 35 U.S.C. 103(a) over Ronaghi (WO 00/43540) in view of Kotewicz (US 5,244,797) and Inouye (US 5,434,070) is withdrawn for at least reason that these references do not teach or suggest using a mixture of RNA dependent polymerases as recited in amended claim 1.

For at least the same reason, the rejections under 35 U.S.C. 103(a) of: claim 20 over Ronaghi, Kotewicz, Inouye and Myers; claims 23 and 24 over Ronaghe, Kotewicz,

Inouye and Malek; and claim 26 over Ronaghe, Kotewicz, Inouye and Rothberg are withdrawn, as these references do not teach or suggest using a mixture of RNA dependent polymerases.

In addition, none of the references teach or suggest the limitation in amended claim 1: "wherein the DNA or RNA primer comprises dATP or ATP that is replaced with alpha-S-dATP". The art does teach substituting alpha-S-dATP for dATP in the *reaction*, such that this nucleotide is incorporated into the *extended* primer, but not in the actual primer sequence itself.

New rejections are set forth below.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7, 14-18, 20 and 23-26 are rejected under 35 U.S.C. 112, 2nd paragraph.

Claim 1 contains the trademark/trade names Superscript™ and Thermoscript™. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods

associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe an RNA dependent polymerase and, accordingly, the identification/description is indefinite. Because all other claims subject to this rejection depend directly or indirectly from claim 1, they are rejected for the same reason.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-7, 14-18, 20 and 23-26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection was previously applied to claims 19 and 21, which have been cancelled. Claim 1 has been amended to recite "wherein the DNA or RNA primer comprises dATP or ATP that is replaced with alpha-S-dATP". There is no support in the original disclosure for such subject matter. Clearly there is support for the presence of alpha-S-dATP in the *reaction* (e.g. the substitution of dATP or ATP in the *reaction* with alpha-S-dATP), such that alpha-S-dATP is incorporated into the *extended* primer (e.g. paragraphs [0074]-[0075] of the published application, and original claim 21, where "the nucleotide" refers to the "at least one nucleotide" by which the primer is extended, recited in original claim 1, step c)). There is also support for the primer comprising dATP, for example the

NUSPT primer (paragraph [0129]) can be seen to contain "A" nucleotides. But the examiner finds no support in the disclosure as filed that the *primer* comprises alpha-S-dATP, which is what the limitation in question implies.

Applicant may obviate this rejection by clearly indicating support for the limitation, or by amending the claim to recite alpha-S-dATP as a component of the reaction, rather than being a part of the primer. For example, claim 1, step (c): "performing at least one primer extension reaction in an extension reaction solution comprising: reagents to detect light triggered by the release of PPi, an RNA-secondary structure reducing agent, and alpha-S-dATP...wherein the alpha-S-dATP is incorporated into the extended DNA or RNA primer...". The "wherein the alpha-S-dATP is incorporated" limitation in the suggested amendment merely stems from its presence in the claim as currently written; retaining this limitation is not required to obviate the rejection. What would be required is the deletion of the phrase "wherein the DNA or RNA primer comprises dATP or ATP that is replaced with alpha-S-dATP". Applicant's representative is especially invited to call the examiner if further assistance or guidance on this issue would be helpful.

Because all other claims subject to this rejection depend directly or indirectly from claim 1, they are rejected for the same reason.

This is a NEW MATTER rejection.

Response to Arguments

Applicant's arguments with respect to claims 1-7, 14-18, 20 and 23-26 have been considered but are moot in view of the new ground(s) of rejection.

It is noted that the rejections over the prior art have been withdrawn in view of the limitation in claim 1: "wherein the DNA or RNA primer comprises dATP or ATP that is replaced with alpha-S-dATP". Should Applicant choose to amend the claims to omit this limitation to obviate the rejection under 35 U.S.C. 112, 1st paragraph, it is possible that the rejections over the prior art could be reinstated. The examiner will review Applicant's arguments prior to such action, and if the arguments are not found persuasive, the examiner will address the arguments at that time.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SAMUEL WOOLWINE whose telephone number is (571)272-1144. The examiner can normally be reached on Mon-Fri 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Samuel Woolwine/
Examiner, Art Unit 1637